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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,370	12/21/2001	Jeffrey A. Trogolo	A-036	5277

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AGION TECHNOLOGIES
60 Audubon Road
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EXAMINER

EBRAHIM, NABILA G

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/032,370	Applicant(s) TROGOLO ET AL.	
	Examiner Nabila G. Ebrahim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-22, 33, 34, 45 and 48-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-22, 33, 34, 45 and 48-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/06 has been entered.

Status of Claims

Claims 1-7, 10-22, 33, 34, 45 and 48-63 are pending in the application.

Claims 8, 9, 23-32, 35-44, 46, 47, and 52 are cancelled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 10-12, 22, 33, 34, 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Hagiwara et al. US 4775585 (Hagiwara).

Hagiwara teaches a polymer article having antibacterial properties as well as a physical property similar to those of the polymer itself, which contains zeolite particles retaining metal-ions, which show an antibacterial effect at the ion-exchange sites of the zeolite particles. The zeolite particles are retaining one or more metal ions having a bactericidal property (col. lines 56-59). The polymer can be highly hydrophilic (col. 8, lines 7+) and the antimicrobial can be a metal salt of a metal having a bactericidal

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activity, such as silver, copper and zinc (col. 3, lines 12+). A particle size of the zeolite can suitably be selected depending on application fields. When granules or coarse fibers, the particle size may be in the range of a few microns to tens microns or even above several hundred microns (col. 4, lines 9+). Note that a fiber is inherently a high aspect ratio particle and that the ratio recited in instant claim 1 as greater than about 2 is also inherent in fibers because the fiber's length is usually -if not mostly- more than double its width or diameter. Note that the definition of fiber is as follows.

Fiber:

Materials: A thin, threadlike piece of any material.

"fiber". Academic Press Dictionary of Science and Technology (1992). Retrieved 28 August 2006, from xreferplus.

<http://www.xreferplus.com/entry/3104363>.

The fibers or the yarns according to Hagiwara can be mix woven, cross woven or union knitted with fibers or yarns having no metal-zeolite to give an antibacterial fiber article with various feelings and functions. This limitation reads on the limitations of instant claims 33, and 34.

Note also that, because Hagiwara uses polyurethane in an antimicrobial composition, it is inherently having water absorption at equilibrium of at least about 20% by weight.

Accordingly, claims 1-4, 10-12, 22, 33, 34, 48, and 49 are anticipated by Hagiwara.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,10-22,33,34,45 and 48-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hagiwara et al. US 4775585 (Hagiwara) in view of Trogolo et al. US 6436422 (Trogolo), Gibson et al US 6413536 (Gibson) and further in view of Michal et al. US 6287285 (Michal).

As discussed above, Hagiwara could make a high aspect ratio antibacterial composition made of a hydrophilic polymer and zeolite particles.

Hagiwara is deficient in disclosing the ceramic type of carrier, the ratio of hydrophilic polymer, the inorganic discoloration inhibiting agent, and the sodium nitrate dopant.

Trogolo discloses an antibiotic coated substrate having an antibiotic coating composition coated thereon. The coating composition is formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite dispersed therein. The antibiotic zeolite may further comprise a discoloration agent (abstract). Antibiotic

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ceramic particles include zeolites, hydroxyapatite, zirconium phosphates and other ion-exchange ceramics. Any suitable hydrophilic polymer may be employed, including hydrophilic polyurethane. Trogo used in the preferred antibiotic zeolite preferred embodiment, ion-exchangeable ions present in zeolite, such as *** sodium ions, calcium ions, potassium ions and iron ions are partially replaced with ammonium and antibiotic metal ions. Such ions may co-exist in the antibiotic zeolite particle since they do not prevent the bactericidal effect. Examples of antibiotic metal ions include, ions of silver, copper, zinc, mercury tin, lead, bismuth, cadmium, chromium and thallium. Preferably, the antibiotic metal ions are silver, copper, or zinc ions, and most preferably silver is employed. These antibiotic metal ions may be incorporated into the zeolite by themselves or in a mixture (col. 3 lines 21-65.) A discoloration agent may be added to the antibiotic hydrophilic polymer. The inorganic discoloration inhibitor is an ion-exchanged ammonium ion in the antibiotic zeolite. The substrate may be any substrate to which the hydrophilic polymer adheres, including glass, plastic, metal, and woven and non-woven fabrics. An article comprising a substrate on which is coated with the antibiotic hydrophilic coating may also be used. The article may be a medical article, such as a catheter, stent, heart valve, or paper (col. 5 lines 22-55.) The solids in the coating solution preferably contain from about 0.01 to about 90% by weight of antibiotic zeolite and from about 10% to about 99.99% by weight of hydrophilic polymer. Trogo discloses a method of altering the release of the antimicrobial because as disclosed in the reference, in medical device embodiments, the coating preferably exhibits a release rate ranging from about 5 to about 50 ppb of microbiocidally effective

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silver ions upon contact of the medical device with body tissues or when contaminated outside of the body with, e.g., microbes transferred from uncovered hands, for a period of more than 1 week (col. 3, lines 43+). However Trogolo does not disclose immersing the particles in a different polymer to alter the release.

Gibson discloses a general teaching of category of biodegradable polymer additives to pharmaceutical compositions. The polymers can be used to alter the release profile of the substance to be delivered, to add integrity to the composition, or to otherwise modify the properties of the composition (col. 15, lines 47+). Also another additive for use with compositions are non-biodegradable polymers. Non-limiting examples of nonerodible polymers which can be used as additives include polyurethanes (col. 16, lines 4+).

It would have been obvious to one of ordinary skills in the art to use the teaching of Gibson by adding the high aspect ratio particles of both Hagiwara and Trogolo into a polymer to alter the release of the particles.

Hagiwara and Trogolo as disclosed above are silent regarding a dopant, specifically sodium nitrate.

Michal discloses a method of providing a therapeutic, diagnostic or lubricious hydrophilic coating on and intra-corporeal medical device (abstract). Additionally, nitric oxide donor drugs may be used as a vasodilator relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. A variety of suitable nitric-oxide donor drugs include sodium nitrate (col. 4).

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Absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Trogolo by adding a dopant specifically sodium nitrate as taught by Michal because of the expectation of relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. Both Trogolo and Michal teach medical devices, specifically medical devices coated with a hydrophilic polymer. Therefore, it would have been obvious to add sodium nitrate to the composition of Kagiwara for the added benefits taught by Michal. The expected result would be a high aspect ratio antimicrobial composition comprising a hydrophilic polymer, an antimicrobial agent and a discoloring agent and a dopant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim

8/28/06



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER